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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,430	01/26/2004	Guillermo J. Tearney	34834/US/2-475387-20	1546

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EXAMINER	
WINAKUR, ERIC FRANK	

ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/765,430	TEARNEY ET AL.	
	Examiner	Art Unit	
	Eric F. Winakur	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9,11-31,33-36 and 40-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,11-31,33-36 and 40-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 - 7, 9, 10 - 31, 33 - 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claim 1, the phrase "the reference arm" (line 12) lacks antecedent basis. With regard to claim 9, it is unclear what further limitation Applicant intends to set forth. With regard to claims 11, 19, 25, and 30, it is noted that the base claim refers to "detecting radiation reflected from the tissue" while birefringence and Doppler shift do not necessarily relate to reflectance measurements. Clarification is required. With regard to claim 18, the phrase "the reference arm" (line 10) lacks antecedent basis. With regard to claims 21 and 22, it is unclear what further positive method step is meant to be set forth. With regard to claim 24, the phrase "the reference arm" (line 12) lacks antecedent basis. With regard to claim 27, it is unclear what limitation of the claimed "storage medium" Applicant intends to set forth, as a "light source" is generally not considered to be a storage medium. With regard to claim 33, it is unclear what limitation of the claimed "logic arrangement" Applicant intends to set forth, as a "light source" is generally not considered to be a logic arrangement.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 18 - 31, and 33 - 35 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. With regard to claims 18 - 23, the claims are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In addition to inquiry of whether a claimed method falls within a judicial exception, Supreme Court precedent (*Diamond v. Diehr,* 450 U.S. 175, 184 (1981); *Parker* v. *Flook,* 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson,* 409 U.S. *63,* 70 (1972); *Cochrane* v. *Deener,* 94 U.S. 780,787-88 (1876).) and recent Federal Circuit decisions, require that a claim drawn to a process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. If neither of these requirements is met by the claim, the method is not a patent eligible process under 35 U.S.C. 101 and is improperly directed to nonstatutory subject matter. Thus, to qualify as a 35 U.S.C. 101 statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied or positively recite the subject matter that is being transformed. As claims 5 and 13 - 24 are not tied to another statutory class, nor do they positively recite subject matter being transformed, they are improperly directed to nonstatutory subject matter.

5. With regard to claims 24 - 29 (storage medium) and 30, 31, and 33 - 35 (logic arrangement), the claims are improperly drawn to non-statutory subject matter. Court decisions related to computer programs, in particular *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994)(discussing patentable weight of data

structure limitations in the context of a statutory claim to a data structure stored on a computer readable medium that increases computer efficiency) and *In re Warmerdam*, 33 F.3d 1354, 1360-61, 31 USPQ2d 1754, 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) and *Warmerdam*, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory) illustrate differences between statutory and non-statutory claims that involve computer programs. In the instant invention, as the claims directed to the storage medium do not positively set forth an indication that the storage medium is a tangible computer-readable medium, the claims appear to be drawn to a data structure claimed as descriptive material *per se*, which is non-statutory (see MPEP 2106.01). Further, the claims directed to the logic arrangement do not define a physical thing, and thus, it must be considered that they merely are directed to an abstract construct. As such, they fail to define an invention within one of the statutory categories (also see MPEP 2106.01).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 - 3, 5 - 7, 9, 11 - 31, 33 - 36, and 40 - 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Izatt et al. (USPN 6,002,480 - cited by Applicant). Izatt et al. teach an optical coherence tomography arrangement that collects one-

dimensional ("A-scan") interferogram data and analyzes the collected data to obtain a backscatter spectrum that is compared against data from 'normal' tissue for diagnostic purposes (column 19, line 49 - column 22, line 11). Details of the process are additionally provided in "Depth Resolved Spectroscopy" (column 16, line 25 - column 18, line 28). The measurement structure is shown in Figure 5. Additionally, Izatt et al. indicate that the device can be implemented as part of an endoscope or catheter instrument (considered to meet the "barrel" embodiment of the claims).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Izatt et al. as applied to claims 1 above. Izatt et al. teach that the measured spectrum is obtained using an arrangement that includes a bank of narrow-band filters (column 24) rather than varying the wavelength of the source (swept wavelength); however, this is merely an alternate equivalent manner to obtain the required spectral data. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Izatt et al. to use a swept wavelength source instead of the source and bank of filters, since it has generally been held to be within the skill level of the art to substitute alternate equivalent expedients.

Response to Arguments

10. Applicant's arguments with respect to claims 1 - 43 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571/272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768